AUG 24 2007

## Summary of Safety and Effectiveness

This summary of safety and effectiveness information is being submitted in accordance with the requirements of The Safety Medical Devices Act of 1990 (SMDA 1990) and 21 CFR Part 807.92.

**Premarket Notification 510(k) Number**: k071913

**Date of Summary Preparation**: August 8, 2007

**Distributor**:
Phadia US Inc.
4169 Commercial Avenue
Portage, MI 49002
269-492-1957

**Manufacturer**:
Phadia AB
Rapsgatan 7
SE-755 50 Uppsala, Sweden

**Company Contact Person**:
Martin Mann
Regulatory Affairs Manager
Phadia US Inc.
4165 Commercial Avenue
Portage, MI 49002
269-492-1957

**Device Name**: ImmunoCAP Allergen f338, Scallop

**Common Name**: Automated *in vitro* quantitative assay for the measurement of allergen specific IgE antibodies.

**Classification**:

| **Product Name** | **Product Code** | **Class** | **CFR** |
|---|---|---|---|
| ImmunoCAP Specific IgE | 82DHB | II | 866.5750 |

**Substantial Equivalence to:** ImmunoCAP Specific IgE (k051218)

**Indications For Use Statement:**

ImmunoCAP Specific IgE is an *in vitro* quantitative assay for the measurement of allergen specific IgE in human serum or plasma. It is intended for *in vitro* diagnostic use as an aid in the clinical diagnosis of IgE mediated allergic disorders in conjunction with

other clinical findings, and is to be used in clinical laboratories, as well as physician office laboratories. ImmunoCAP Allergen f338, Scallop is to be used with the ImmunoCAP Instrument System, ImmunoCAP 100$^{e}$, ImmunoCAP 250, and ImmunoCAP 1000.

## General Description:

### Reagents

ImmunoCAP Specific IgE reagents are modular in concept and are available individually. For a complete listing of reagents needed to perform the Phadia ImmunoCAP Specific IgE assay, please consult the ImmunoCAP Specific IgE Conjugate Directions for Use.

### Instrument System

ImmunoCAP 100$^{e}$, ImmunoCAP 250, and ImmunoCAP 1000 instruments, with built-in software, process all steps of the assay and print results automatically after the assay is completed.

### ImmunoCAP Specific IgE, Test Principle

The allergen of interest, covalently coupled to ImmunoCAP, reacts with the specific IgE in the patient sample. After washing away non-specific IgE, enzyme labeled antibodies against IgE are added to form a complex. After incubation, unbound enzyme-anti-IgE is washed away and the bound complex is then incubated with a developing agent. After stopping the reaction, the fluorescence of the eluate is measured. The higher the response value, the more specific IgE is present in the specimen. To evaluate the test results, the responses for the patient samples are transformed to concentrations with the use of a calibration curve.

### Device Description

The safety and effectiveness of the cleared device, ImmunoCAP Specific IgE system for the determination of specific IgE antibodies, have been established in previous 510(k) submissions. This submission covers the addition of a new allergen, ImmunoCAP Allergen, f338, Scallop to the existing ImmunoCAP Specific IgE assay. No changes are made to the Intended Use or in the Indications for Use statements.

The new ImmunoCAP Allergen, f338, Scallop was characterized with the use of samples from patients with case histories of suspected clinical reactions to scallop and/or food intolerance, as well as samples from healthy, non-sensitized donors. Inhibition studies verified the immunological specificity of scallop specific IgE antibody binding.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Phadia US Inc.
c/o Mr. Martin Mann
Regulatory Affairs Manager
4165 Commercial Avenue
Portage, MI 49002

AUG 24 2007

Re: k071913
Trade/Device Name: ImmunoCAP Allergen f338, Scallop
Regulation Number: 21 CFR 866.5750
Regulation Name: Radioallergosorbent (RST) Immunological Test System
Regulatory Class: Class II
Product Code: DHB
Dated: July 02, 2007
Received: July 11, 2007

Dear Mr. Mann:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The

FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Maria M. Chan for
Dr. Robert Becker

Robert L. Becker, Jr., M.D., Ph.D.
Director
Division of Immunology and Hematology Devices
Office of In Vitro Diagnostic Device Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

# Indication for Use

510(k) Number (if known): k071913

Device Name: ImmunoCAP Allergen f338, Scallop

Indication For Use:

ImmunoCAP Specific IgE is an *in vitro* quantitative assay for the measurement of allergen specific IgE in human serum or plasma. It is intended for *in vitro* diagnostic use as an aid in the clinical diagnosis of IgE mediated allergic disorders in conjunction with other clinical findings, and is to be used in clinical laboratories, as well as physician office laboratories. ImmunoCAP Allergen f338, Scallop is to be used with the ImmunoCAP Instrument System, ImmunoCAP 100, ImmunoCAP 250, and ImmunoCAP 1000.

Prescription Use ___√___ And/Or Over the Counter Use ____.
(21 CFR Part 801 Subpart D) (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety